DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

October 25, 2002

WARNING LETTER NYK 2003-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Kendall S. Cody, Owner
Kendall S. Cody
2966 Fenner Road
Cazenovia, NY 13035

An investigation was conducted at your dairy farm operation located on Fenner Road, Cazenovia, New York, by U.S. Food and Drug Administration (FDA) Investigator Bruce G. Cooper on August 15-29, 2002. The investigation confirmed that you offered a cow for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act); and that you have caused an animal drug to become adulterated within the meaning of Section 501(a)(5) of the Act.

On or about May 29, 2002 you sold a cow bearing tag No. 652 to [redacted] where ear tag No. [redacted] and back tag No. 306 were attached to the cow. This cow was subsequently delivered to and slaughtered at [redacted] on May 30, 2002. USDA analysis of tissue samples from that animal revealed the presence of the drug sulfadimethoxine at a level of 7.66 ppm in the liver and 10.16 ppm in the muscle. These exceed the 0.1 ppm tolerance identified in 21 Code of Federal Regulations (CFR) 556.640 by more than 76 times and 101 times, respectively. The presence of sulfadimethoxine at these levels in uncooked edible tissues of cattle causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

On or about March 24, 2001 you provided [redacted] a signed Livestock Owner's Certificate. This certificate certified that none of the livestock shipped or delivered to [redacted] would be adulterated within the meaning of the Act and that none of the livestock will have an illegal level of drug residues. On or about May 29, 2002 you sold this cow adulterated with these residues to [redacted]

Our investigation found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack a system for assuring that drugs are used in a manner not contrary to label instructions, and for assuring animals medicated on your farm have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous drug residues from edible tissues. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

Our investigation also revealed you adulterated the drugs sulfadimethoxine and penicillin G procaine within the meaning of Section 501(a)(5) of the Act when you used the drugs in an extralabel manner without veterinary supervision. Your use of drugs in dairy cows at higher than labeled dosages causes the drugs to be unsafe to use.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to achieve prompt corrective action may result in regulatory action – without further notice. This may include seizure and injunction.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, it is your responsibility to assure your operations are in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. As a dairy farmer, you are the individual who introduces or offers for introduction into interstate commerce the adulterated animal. It is not necessary for you to personally ship an animal into interstate commerce to be responsible for violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to an auction barn and/or slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for violation of the Act.

Please notify this office in writing, within 15 working days, of the steps you have taken, or intend to take, to prevent a recurrence of these or similar violations. Your written response should be directed to Patricia A. Clark, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Suite 100, Buffalo, New York 14202, telephone 716-551-4461, ext. 3168.

Sincerely,

Jerome G. Woyshner
District Director